

## PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

To:

GILSON, David, Grant  
Spoor and Fisher  
Rochester Place  
173 Rivonia Road, Morningside  
Sandton, P.O. Box 41312  
2024 Craighall  
AFRIQUE DU SUD

Date of mailing (day/month/year) 18 October 2001 (18.10.01)	<b>IMPORTANT NOTIFICATION</b>
Applicant's or agent's file reference W/D/127	
International application No. PCT/IB00/00287	International filing date (day/month/year) 17 March 2000 (17.03.00)

## 1. The following indications appeared on record concerning:

☒ the applicant      ☒ the inventor      ☐ the agent      ☐ the common representative

Name and Address REYNOLDS, Stanford, William,	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

## 2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☒ the person      ☐ the name      ☐ the address      ☐ the nationality      ☐ the residence

Name and Address REYNOLDS, Stanford, William,	State of Nationality ZA	State of Residence ZA
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

## 3. Further observations, if necessary:

**The applicant/inventor for US only.**

## 4. A copy of this notification has been sent to:

☒ the receiving Office      ☐ the designated Offices concerned  
☐ the International Searching Authority      ☒ the elected Offices concerned  
☐ the International Preliminary Examining Authority      ☐ other:

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Ki-Nam HA Telephone No.: (41-22) 338.83.38
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## PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

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## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner  
 US Department of Commerce  
 United States Patent and Trademark  
 Office, PCT  
 2011 South Clark Place Room  
 CP2/5C24  
 Arlington, VA 22202  
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

<b>Date of mailing</b> (day/month/year) 15 November 2000 (15.11.00)	
<b>International application No.</b> PCT/IB00/00287	<b>Applicant's or agent's file reference</b> W/D/127
<b>International filing date</b> (day/month/year) 17 March 2000 (17.03.00)	<b>Priority date</b> (day/month/year) 17 March 1999 (17.03.99)
<b>Applicant</b> DUGMORE, Peter, Balfour et al	

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

12 October 2000 (12.10.00)



in a notice effecting later election filed with the International Bureau on:

2. The election
- ☒
- was



was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Zakaria EL KHODARY Telephone No.: (41-22) 338.83.38
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## PATENT COOPERATION TREATY

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REC'D 03 AUG 2001

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PA129282/PCT	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IB00/00287	International filing date (day/month/year) 17/03/2000	Priority date (day/month/year) 17/03/1999
International Patent Classification (IPC) or national classification and IPC A61M25/06		
Applicant DUGMORE, Peter, Balfour et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 12/10/2000	Date of completion of this report 31.07.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Ehrsam, F Telephone No. +49 89 2399 2343 

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB00/00287

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
- Description, pages:**

1-12 as originally filed

### Claims, No.:

20 as originally filed

1-19 with telefax of 19/04/2001

### Drawings, sheets:

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB00/00287

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

**see separate sheet**

6. Additional observations, if necessary:

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes:	Claims	1-19
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-19
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations  
**see separate sheet**

## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/IB00/00287

See point V of the report:

The Applicant has suppressed the following features from claim 1:

- a) mountable to the rear end of the syringe (see original claim 1)

The scope of this claim has therefore been extended. No basis for such an extension can be found in the application as filed and hence the claim as amended results in the application being amended in such a way that it contains subject-matter which extends beyond the content of the application as filed, contrary to Article 34 (2) b) PCT.

See point V of the report:

1. The present application does not meet the requirements of Article 33 (2) PCT, because the subject-matter of claims 1 and 2 is not new in the sense of Article 33 (2) PCT. Indeed, document US-A-4762516 (D1) discloses all the features of claims 1 and 22, in particular figures 1 to 4 show all the features of the present claims 1 and 2 (see also description col. 2, line 9 to col. 3, line 5). The same objection applies to US-A-5769827 (D2), see in particular the abstract and the figures.
2. The subject-matter of claims 1 to 19 lacks inventive step (Art. 33 (3) PCT).  
A safety assembly for a hypodermic applicator is already known from the document US-A-4762516 D1, see in particular figures 1 to 4 show the features of the preamble of present claim 1 (see also description col. 2, line 9 to col. 3, line 5).  
The sole difference of the subject-matter of claim 1 over D1 is the that the retractor is detachably mounted to the needle seat and being separable from the needle seat when in the retracted position.  
However, if the skilled man would wish to improve the assembly, he would have used the known separable connection as disclosed in US-A-5403283 (D10), col. 8, line 39 to col. 9 line 40 and Figures 11 to 13. One skilled in the art would have thus arrived at the assembly of the present invention.  
The subject-matter of the above mentioned claims does therefore not appear to involve an inventive step.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/IB00/00287

See point VII of the report:

1. The description should have been brought into conformity with the new claims to be filed; care should be taken during revision, especially of the introductory portion including any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Art. 34 2) b)).
2. To meet the requirements of Rules 6 3 b) the independent claim should have been properly cast in a two part form, with those features which in combination are part of the nearest prior art being placed in the first part.
3. To meet the requirements of Rule 5.1 a vi, the cited documents should have been identified in the description and the relevant background art therein is to be indicated.
4. The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

**CLAIMS**

1. A safety assembly for a hypodermic applicator set comprising a needle assembly including a needle seat from which a hollow needle extends, an elongate retractor which is mountable to the needle seat, a safety shield for housing the needle assembly slidably within a chamber defined therein and having a front end through which the needle is arranged to project and a rear open end through which the elongate retractor extends into mounting engagement with the needle seat, and at least one captivating formation carried on the shield, the needle assembly being slidably moveable in concert with the retractor from an extended administrable position in which the needle extends through the front end of the shield to a retracted position in which the needle is fully withdrawn into the chamber by the retractor to be held safely captive within the chamber by the captivating formation, the retractor being detachably mounted to the needle seat and being separable from the needle seat when in the retracted position.
2. A safety assembly according to claim 1 in which the retractor includes a pair of manually grippable outer caliper arms which are arranged to deform inwardly in response to finger pressure so as to frictionally engage an outer surface of the safety shield when the needle assembly is in the extended administrable position, and a central shaft or plunger which extends into the chamber and terminates in a needle seat engaging formation.
3. A safety assembly according to claim 2 in which the needle assembly and the retractor are in conjunction freely and axially slidable from the extended to the retracted positions, the caliper arms having an inner arcuate profile which corresponds to an outer arcuate profile of the safety shield.
4. A safety assembly according to either one of claims 2 or 3 in which a needle shield is fitted over the needle when in an extended position, the needle shield being mountable to a front end of the safety shield or retractor and including detent means for detaining the needle assembly in an extended stowed position prior to use.



5. A safety assembly according to claim 4 in which the needle shield and the retractor carry respective engaging and complementary engaging formations constituting the detent means for detachably engaging one another when the safety assembly is in the extended stowed position.
6. A safety assembly according to claim 5 in which the outer caliper arms terminate in the complementary engaging formations for engaging with engaging formations on the needle shield.
7. A safety assembly according to claim 6 in which the needle seat defines a viewing chamber for monitoring the ingress of fluid via the hollow needle, and fluid retaining filter insert means is mounted at a rear end of the viewing chamber, the filter insert means being held in position by the needle seat engaging formation at a front end of the plunger.
8. A safety assembly according to claim 7 in which the filter insert means comprises an air permeable filter disc which is mounted in a detent towards a rear end of the viewing chamber.
9. A safety assembly according to claim 8 in which the needle seat engaging formation comprises a balled end formation which is detachably engageable with a corresponding socket recess defined at a rear end of the viewing chamber, and at least one breather gap being defined between the balled end formation and the socket recess, with the combination of the air permeable filter disc and the breather gap providing an air escape path as fluid is introduced into the viewing chamber.
10. A safety assembly according to any one of the preceding claims in which the hypodermic applicator set is a hypodermic cannula set, the needle extends through a spigot defining a finger barrier at the front end of the safety shield, and a cannula or catheter tube is detachably mountable to the spigot.
11. A safety assembly according to claim 10 in which a sealing plug is located towards the front end of the chamber for preventing the leakage of fluid from the catheter tube into the chamber, the needle extending in use through the sealing

awable back through the sealing  
 arp end of the needle is seated  
 ug being arranged to reseal on

ilch the sealing plug serves as a  
 eedle from escaping through the  
 ed position.

o preceding claims in which the  
 ending inwardly from a rear end  
 at a rearmost end of the needle  
 with the inner wall surface of the  
 one breather gap for preventing  
 e chamber between the needle

for a hypodermic applicator set  
 having a front spigot end and a  
 i spigot end of the safety shield,  
 needle projecting from a needle  
 nd driving the needle assembly  
 tends through the catheter tube  
 ft which detachably engages a  
 dle seat.

s the further steps of fitting a  
 a rear end of the needle shield

4 or 15 in which the method  
 sc to the needle by piercing a  
 , and using the needle as a  
 ling disc.

17. A method according to claim 16 which includes the further step of locating the sealing disc towards the front end of a chamber defined within the safety shield for preventing the leakage of fluid from the catheter tube into the chamber once the needle is withdrawn into the retracted position.
18. A method according to any one of the preceding claims 14 to 17 in which the method includes the further step of punching a filter disc from a sheet of disc material, locating the filter disc within the needle seat, and retaining the filter disc in position within the needle seat by virtue of the engagement between the central plunger or shaft and the complementary formation at the rear end of the needle seat.
19. A method according to any one of claims 14 to 18 in which the assembly steps take place on a carousel having a plurality of stations, at which the various components are up- or downloaded.

**CLAIMS**

1. A safety assembly for a hypodermic applicator set comprising a needle assembly including a needle seat from which a hollow needle extends, an elongate retractor which is mountable to the needle seat, a safety shield for housing the needle assembly slidably within a chamber defined therein and having a front end through which the needle is arranged to project and a rear open end through which the elongate retractor extends into mounting engagement with the needle seat, and at least one captivating formation carried on the shield, the needle assembly being slidably moveable in concert with the retractor from an extended administrable position in which the needle extends through the front end of the shield to a retracted position in which the needle is fully withdrawn into the chamber by the retractor to be held safely captive within the chamber by the captivating formation.
2. A safety assembly according to claim 1 in which the retractor is detachably mountable to a rear end of the needle seat and is separable from the needle seat when in the retracted position.
3. A safety assembly according to either one of claims 1 or 2 in which the retractor includes a pair of manually grippable outer caliper arms which are arranged to deform inwardly in response to finger pressure so as to frictionally engage an outer surface of the safety shield when the needle assembly is in the extended administrable position, and a central shaft or plunger which extends into the chamber and terminates in a needle seat engaging formation.
4. A safety assembly according to claim 3 in which the needle assembly and the refractor are in conjunction freely and axially slidable from the extended to the retracted positions, the caliper arms having an inner

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arcuate profile which corresponds to an outer arcuate profile of the safety shield.

5. A safety assembly according to either one of claims 3 or 4 in which a needle shield is fitted over the needle when in an extended position, the needle shield being mountable to a front end of the safety shield or retractor and including detent means for detaining the needle assembly in an extended stowed position prior to use.
6. A safety assembly according to claim 5 in which the needle shield and the retractor carry respective engaging and complementary engaging formations constituting the detent means for detachably engaging one another when the safety assembly is in the extended stowed position.
7. A safety assembly according to claim 6 in which the outer caliper arms terminate in the complementary engaging formations for engaging with engaging formations on the needle shield.
8. A safety assembly according to claim 7 in which the needle seat defines a viewing chamber for monitoring the ingress of fluid via the hollow needle, and fluid retaining filter insert means is mounted at a rear end of the viewing chamber, the filter insert means being held in position by the needle seat engaging formation at a front end of the plunger.
9. A safety assembly according to claim 8 in which the filter insert means comprises an air permeable filter disc which is mounted in a detent towards a rear end of the viewing chamber.
10. A safety assembly according to claim 9 in which the needle seat engaging formation comprises a balled end formation which is

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detachably engageable with a corresponding socket recess defined at a rear and of the viewing chamber, and at least one breather gap being defined between the balled end formation and the socket recess, with the combination of the air permeable filter disc and the breather gap providing an air escape path as fluid is introduced into the viewing chamber.

11. A safety assembly according to any one of the preceding claims in which the hypodermic applicator set is a hypodermic cannula set, the needle extends through a spigot defining a finger barrier at the front end of the safety shield, and a cannula or catheter tube is detachably mountable to the spigot.
12. A safety assembly according to claim 11 in which a sealing plug is located towards the front end of the chamber for preventing the leakage of fluid from the catheter tube into the chamber, the needle extending in use through the sealing plug in the extended position and being withdrawable back through the sealing plug to the retracted position in which the sharp end of the needle is seated rearwardly of the sealing plug, the sealing plug being arranged to reseal on withdrawal of the needle.
13. A safety assembly according to claim 12 in which the sealing plug serves as a front captivating formation for preventing the needle from escaping through the front end of the safety shield when in the retracted position.
14. A safety assembly according to any one of the preceding claims in which the captivating means comprises a retaining rib extending inwardly from a rear end of the shield, and a rearmost flange is formed at a rearmost end of the needle assembly, the flange forming a snug

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sliding fit with the inner wall surface of the safety shield and being provided with at least one breather gap for preventing the formation of a vacuum in that portion of the chamber between the needle assembly and the shield

15. A method of manufacturing a safety assembly for a hypodermic applicator set comprising the steps of providing a safety shield having a front spigot end and a rear open end, fitting a catheter tube to the front spigot end of the safety shield, loading a needle assembly, which includes a needle projecting from a needle seat, through the rear open end of the shield, and driving the needle assembly into an extended position in which the needle extends through the catheter tube using a retractor having a central plunger or shaft which detachably engages a complementary formation at a rear end of the needle seat.
16. A method according to claim 15 which includes the further steps of fitting a needle shield over the needle and catheter, with a rear end of the needle shield detachably engaging a front end of the retractor.
17. A method according to either one of claims 15 or 16 in which the method includes the further steps of fitting a sealing disc to the needle by piercing a sheet of disc-forming material with the needle, and using the needle as a centering axis for punching or cutting out the sealing disc.
18. A method according to claim 17 which includes the further step of locating the sealing disc towards the front end of a chamber defined within the safety shield for preventing the leakage of fluid from the catheter tube into the chamber once the needle is withdrawn into the retracted position.

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19. A method according to any one of the preceding claims 15 to 18 in which the method includes the further step of punching a filter disc from a sheet of disc material, locating the filter disc within the needle seat, and retaining the filter disc in position within the needle seat by virtue of the engagement between the central plunger or shaft and the complementary formation at the rear end of the needle seat.
20. A method according to any one of claims 15 to 19 in which the assembly steps take place on a carousel having a plurality of stations, at which the various components are up- or downloaded.



# INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 00/00287

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 7    A61M25/06    A61M5/32		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC 7    A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 762 516 A (CHOKSI PRADIP V ET AL) 9 August 1988 (1988-08-09) column 2, line 9 -column 3, line 5; figures 1-4 ---	1,2
X	US 5 769 827 A (DEMICHELE LOUIS R ET AL) 23 June 1998 (1998-06-23) abstract ---	1
Y	US 4 944 728 A (CARRELL MICHAEL W ET AL) 31 July 1990 (1990-07-31) abstract ---	1-14
Y	GB 2 202 747 A (DUCAT DR WILLIAM) 5 October 1988 (1988-10-05) page 5, line 16 - line 20; figure 4 --- -/--	1-14
<div style="display: flex; justify-content: space-between;"> <span><input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.</span> <span><input checked="" type="checkbox"/> Patent family members are listed in annex.</span> </div>		
<div style="display: flex;"> <div style="flex: 1;"> <p>* Special categories of cited documents :</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="flex: 1;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p> </div> </div>		
Date of the actual completion of the international search  <div style="text-align: center; font-weight: bold;">20 June 2000</div>		Date of mailing of the international search report  <div style="text-align: center; font-weight: bold;">30/06/2000</div>
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer  <div style="text-align: center; font-weight: bold;">Ehrsam, F</div>

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/80/00287

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 382 190 A (SAFETYJECT) 16 August 1990 (1990-08-16) abstract ----	1
A	US 4 944 725 A (MCDONALD MICHAEL) 31 July 1990 (1990-07-31) the whole document ----	1-14
A	EP 0 827 759 A (BECTON DICKINSON CO) 11 March 1998 (1998-03-11) abstract; figures 1-9 ----	1-14 15,16
X	EP 0 521 596 A (CRITIKON INC) 7 January 1993 (1993-01-07) abstract; figures 1-4 ----	1-10
A	WO 92 09320 A (NUJENKO PTY LTD) 11 June 1992 (1992-06-11) figures 14-16 ----	10
A	US 5 403 283 A (LUTHER RONALD B) 4 April 1995 (1995-04-04) figures 5-10 ----	1
A	DE 44 34 569 A (BECTON DICKINSON CO) 30 March 1995 (1995-03-30) figures 8-10 -----	12

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/JP98/00287

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4762516	A	09-08-1988	AT 76310 T AU 617662 B AU 1259388 A BR 8800968 A CA 1297366 A CN 1017403 B DE 3871185 A EP 0281421 A GR 3005441 T JP 1873810 C JP 5088627 B JP 63229062 A KR 9411285 B MX 171801 B NZ 223656 A PH 24619 A PT 86876 A,B US 4832696 A ZA 8801559 A	15-06-1992 05-12-1991 08-09-1988 11-10-1988 17-03-1992 15-07-1992 25-06-1992 07-09-1988 24-05-1993 26-09-1994 22-12-1993 22-09-1988 05-12-1994 16-11-1993 26-04-1991 17-08-1990 30-03-1989 23-05-1989 29-03-1989
US 5769827	A	23-06-1998	US 6010487 A	04-01-2000
US 4944728	A	31-07-1990	NONE	
GB 2202747	A	05-10-1988	NONE	
EP 0382190	A	16-08-1990	US 4917669 A AU 631841 B AU 4922590 A BR 9000542 A CA 2009451 A DE 69023781 D JP 1750555 C JP 2277463 A JP 4036031 B MX 167201 B US RE34223 E	17-04-1990 10-12-1992 16-08-1990 15-01-1991 08-08-1990 11-01-1996 08-04-1993 14-11-1990 12-06-1992 09-03-1993 13-04-1993
US 4944725	A	31-07-1990	US 4834718 A	30-05-1989
EP 0827759	A	11-03-1998	US 5797880 A CA 2213942 A JP 10137342 A	25-08-1998 05-03-1998 26-05-1998
EP 0521596	A	07-01-1993	US 5120319 A AU 651866 B AU 1130792 A CA 2061811 A DE 69210114 D DE 69210114 T JP 5096011 A	09-06-1992 04-08-1994 07-01-1993 27-12-1992 30-05-1996 14-08-1996 20-04-1993
WO 9209320	A	11-06-1992	DK 285990 A AT 168020 T AU 667296 B AU 9045891 A CA 2099587 A DE 69129752 D	31-05-1992 15-07-1998 21-03-1996 25-06-1992 31-05-1992 13-08-1998

# INTERNATIONAL SEARCH REPORT

inform patent family members

Inter Application No  
PCT/ 00/00287

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9209320 A		EP 0559734 A JP 6504923 T US 5531705 A	15-09-1993 09-06-1994 02-07-1996
US 5403283 A	04-04-1995	AU 688360 B AU 7470694 A CA 2174229 A EP 0725659 A JP 10503094 T WO 9511710 A US 5569217 A	12-03-1998 22-05-1995 04-05-1995 14-08-1996 24-03-1998 04-05-1995 29-10-1996
DE 4434569 A	30-03-1995	CA 2133053 A FR 2710541 A JP 2584597 B JP 7163665 A	30-03-1995 07-04-1995 26-02-1997 27-06-1995

## PATENT COOPERATION TREATY

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Draw file

Y N

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

Gilson, David, G. et al.  
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NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing  
(day/month/year)

31.07.2001

Applicant's or agent's file reference  
PA129262/PCT

## IMPORTANT NOTIFICATION

International application No.  
PCT/IB00/00287International filing date (day/month/year)  
17/03/2000Priority date (day/month/year)  
17/03/1999

Applicant

DUGMORE, Peter, Balfour et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

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## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PA129282/PCT		<b>FOR FURTHER ACTION</b>		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB00/00287	International filing date (day/month/year) 17/03/2000	Priority date (day/month/year) 17/03/1999		
International Patent Classification (IPC) or national classification and IPC A61M25/06				
Applicant DUGMORE, Peter, Balfour et al.				
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 4 sheets.</p>				
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input checked="" type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>				
Date of submission of the demand  12/10/2000		Date of completion of this report  31.07.2001		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer  Ehrsam, F  Telephone No. +49 89 2399 2343		



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/IB00/00287

**I. Basis of the report**

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
- Description, pages:**

1-12 as originally filed

**Claims, No.:**

20 as originally filed

1-19 with telefax of 19/04/2001

**Drawings, sheets:**

1/5-5/5 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the International preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**International application No. **PCT/IB00/00287**

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

**see separate sheet**

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims 1-19
	No:	Claims
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-19
Industrial applicability (IA)	Yes:	Claims 1-20
	No:	Claims

- 2. Citations and explanations**  
**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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See point V of the report:

The Applicant has suppressed the following features from claim 1:

- a) mountable to the rear end of the syringe (see original claim 1)

The scope of this claim has therefore been extended. No basis for such an extension can be found in the application as filed and hence the claim as amended results in the application being amended in such a way that it contains subject-matter which extends beyond the content of the application as filed, contrary to Article 34 (2) b) PCT.

See point V of the report:

1. The present application does not meet the requirements of Article 33 (2) PCT, because the subject-matter of claims 1 and 2 is not new in the sense of Article 33 (2) PCT. Indeed, document US-A-4762516 (D1) discloses all the features of claims 1 and 22, in particular figures 1 to 4 show all the features of the present claims 1 and 2 (see also description col. 2, line 9 to col. 3, line 5). The same objection applies to US-A-5769827 (D2), see in particular the abstract and the figures.
2. The subject-matter of claims 1 to 19 lacks inventive step (Art. 33 (3) PCT).  
A safety assembly for a hypodermic applicator is already known from the document US-A-4762516 D1, see in particular figures 1 to 4 show the features of the preamble of present claim 1 (see also description col. 2, line 9 to col. 3, line 5).  
The sole difference of the subject-matter of claim 1 over D1 is that the retractor is detachably mounted to the needle seat and being separable from the needle seat when in the retracted position.  
However, if the skilled man would wish to improve the assembly, he would have used the known separable connection as disclosed in US-A-5403283 (D10), col. 8, line 39 to col. 9 line 40 and Figures 11 to 13. One skilled in the art would have thus arrived at the assembly of the present invention.  
The subject-matter of the above mentioned claims does therefore not appear to involve an inventive step.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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See point VII of the report:

1. The description should have been brought into conformity with the new claims to be filed; care should be taken during revision, especially of the introductory portion including any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Art. 34 2) b)).
2. To meet the requirements of Rules 6 3 b) the independent claim should have been properly cast in a two part form, with those features which in combination are part of the nearest prior art being placed in the first part.
3. To meet the requirements of Rule 5.1 a vi, the cited documents should have been identified in the description and the relevant background art therein is to be indicated.
4. The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

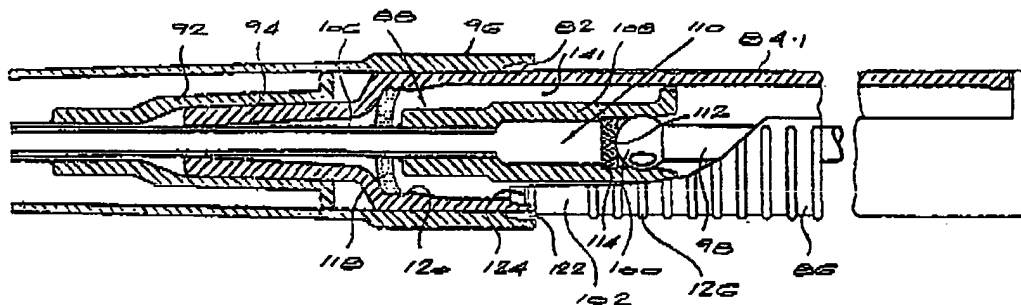
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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/IB00/00287 (22) International Filing Date: 17 March 2000 (17.03.00) (30) Priority Data: 99/2146 17 March 1999 (17.03.99) ZA (71)(72) Applicants and Inventors: DUGMORE, Peter, Balfour [ZA/ZA]; 4 Swanmore Road, Rondebosch, 7700 Cape Town (ZA). BULL, Anthony, Eric [ZA/ZA]; 31 Grotto Road, Rondebosch, 7700 Cape Town (ZA). REYNOLDS, Stanford, William, Gladwin [ZA/ZA]; 18 Hopson Road, 3630 Westville (ZA). (74) Agents: GILSON, David, Grant et al.; Spoor and Fisher, Rochester Place, 173 Rivonia Road, Morningside, Sandton, P.O. Box 41312, 2024 Craighall (ZA).	(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  Published With international search report.	

(54) Title: A SAFETY ASSEMBLY FOR A HYPODERMIC APPLICATOR SET



## (57) Abstract

A cannula safety assembly (82) includes a cannula safety shield (84) and an elongate retractor (86). The retractor (86) is provided with a central plunger (98) which extends through a rear open end (85) of the safety shield and a pair of caliper arms (102) which fit over the safety shield. A needle assembly (88) includes a needle seat (108) from which a hollow needle (106) extends so that the needle assembly (88) is mounted detachably to the front end of the plunger (98), and the needle shield (96) is fitted over the front end of the safety shield, and mounted detachably to the ends of the caliper arms (102). The needle assembly (88) is slidably moveable in concert with the retractor (86) from an extended administrable position to a retracted position in which the needle (106) is fully withdrawn into the safety shield chamber by the retractor to be held safely captive within the chamber. The retractor is separable from the needle seat when in the retracted position. The invention extends to a method of manufacturing a cannula safety assembly.

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## A SAFETY ASSEMBLY FOR A HYPODERMIC APPLICATOR SET

### BACKGROUND OF THE INVENTION

THIS invention relates to a safety assembly for a hypodermic applicator set, and in particular to a safety assembly for a hypodermic cannula set.

The needles of used syringes and cannula infusion and fluid extraction sets pose an increasing threat of transmissibility of potentially lethal infections such as HIV and hepatitis B viruses to persons handling the devices both during and after use.

In the recent past, a vast array of devices and systems for preventing contact with used needles of medical devices have been proposed. These include syringes and cannula devices extending to protecting shields or sheaths into which the devices are withdrawn after use to a position where the needle point is shrouded from accidental contact. Such shielding devices have tended to focus on syringe sets as opposed to cannula sets, in spite of the fact that the latter constitute a greater risk in view of the greater quantities of potentially contaminated blood involved and the generally jerkier movements associated with the necessity to withdraw the needle quickly from the cannula catheter and to prevent blood emission or fluid spillage while simultaneously connecting a fluid infusion or extraction tube to the catheter.

In the case of both syringe sets and cannula sets, the additional operating length of the device constituted by the protecting shield, and the additional components in the retraction mechanism employed, have contributed both to significant additional manufacturing costs and also to user inconvenience.

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It is an object of the invention to provide a safety assembly for a hypodermic cannula set in which the risk of needle stick is minimized after the needle has been in contact with potentially infected blood, which is economical to produce and which is simple and convenient to use, in that the procedure does not significantly deviate from conventional catheter or cannula insertion techniques.

### SUMMARY OF THE INVENTION

According to a first aspect of the invention there is provided a safety assembly for a hypodermic applicator set comprising a needle assembly including a needle seat from which a hollow needle extends, an elongate retractor which is mountable to the needle seat, a safety shield for housing the needle assembly slidably within a chamber defined therein and having a front end through which the needle is arranged to project and a rear open end through which the elongate retractor extends into mounting engagement with the needle seat, and at least one captivating formation carried on the shield, the needle assembly being slidably moveable in concert with the retractor from an extended administrable position in which the needle extends through the front end of the shield to a retracted position in which the needle is fully withdrawn into the chamber by the retractor to be held safely captive within the chamber by the captivating formation.

In the preferred form of the invention, the retractor is detachably mountable to a rear end of the needle seat and is separable from the needle seat when in the retracted position.

Conveniently, the retractor includes a pair of manually grippable outer caliper arms which are arranged to deform inwardly in response to finger pressure so as to frictionally engage an outer surface of the safety shield when the needle

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assembly is in the extended administrable position, and a central shaft or plunger which extends into the chamber and terminates in a needle seat engaging formation.

Advantageously the needle assembly and the retractor are in conjunction freely and axially slidable from the extended to the retracted positions, the caliper arms having an inner arcuate profile which corresponds to an outer arcuate profile of the safety shield.

Preferably, a needle shield is fitted over the needle when in an extended position, the needle shield being mountable to a front end of the safety shield or retractor and including detent means for detaining the needle assembly in an extended stowed position prior to use.

Typically, the needle shield and the retractor carry respective engaging and complementary engaging formations constituting the detent means for detachably engaging one another when the safety assembly is in the extended stowed position.

Advantageously, the outer caliper arms terminate in the complementary engaging formations for engaging with engaging formations on the needle shield.

Conveniently, the needle seat defines a viewing chamber for monitoring the ingress of fluid via the hollow needle, and fluid retaining filter insert means is mounted at a rear end of the viewing chamber, the filter insert means being held in position by the needle seat engaging formation at a front end of the plunger.

The filter insert means may comprise an air permeable filter disc which is mounted in a detent towards a rear end of the viewing chamber.

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Conveniently, the needle seat engaging formation comprises a balled end formation which is detachably engageable with a corresponding socket recess defined at a rear end of the viewing chamber, and at least one breather gap being defined between the balled end formation and the socket recess, with the combination of the air permeable filter disc and the breather gap providing an air escape path as fluid is introduced into the viewing chamber.

Typically, the hypodermic applicator set is a hypodermic cannula set, the needle extends through a spigot defining a finger barrier at the front end of the safety shield, and a cannula or catheter tube is detachably mountable to the spigot.

Advantageously, a sealing plug is located towards the front end of the chamber for preventing the leakage of fluid from the catheter tube into the chamber, the needle extending in use through the sealing plug in the extended position and being withdrawable back through the sealing plug to the retracted position in which the sharp end of the needle is seated rearwardly of the sealing plug, the sealing plug being arranged to reseal on withdrawal of the needle.

The sealing plug may serve as a front captivating formation for preventing the needle from escaping through the front end of the safety shield when in the retracted position.

Advantageously, the captivating means comprises a retaining rib extending inwardly from a rear end of the shield, and a rearmost flange is formed at a rearmost end of the needle assembly, the flange forming a snug sliding fit with the inner wall surface of the safety shield and being provided with at least one breather gap for preventing the formation of a vacuum in that portion of the chamber between the needle assembly and the shield.



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The invention extends to a method of manufacturing a safety assembly for a hypodermic applicator set comprising the steps of providing a safety shield having a front spigot end and a rear open end, fitting a catheter tube to the front spigot end of the safety shield, loading a needle assembly, which includes a needle projecting from a needle seat, through the rear open end of the shield, and driving the needle assembly into an extended position in which the needle extends through the catheter tube using a retractor having a central plunger or shaft which detachably engages a complementary formation at a rear end of the needle seat.

Preferably, the further steps of fitting a needle shield over the needle and catheter, with a rear end of the needle shield detachably engaging a front end of the retractor.

The method advantageously includes the further steps of fitting a sealing disc to the needle by piercing a sheet of disc-forming material with the needle, and using the needle as a centering axis for punching or cutting out the sealing disc.

Conveniently, the method includes the further step of locating the sealing disc towards the front end of a chamber defined within the safety shield for preventing the leakage of fluid from the catheter tube into the chamber once the needle is withdrawn into the retracted position.

The method may include the further step of punching a filter disc from a sheet of disc material, locating the filter disc within the needle seat, and retaining the filter disc in position within the needle seat by virtue of the engagement between the central plunger or shaft and the complementary formation at the rear end of the needle seat.

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Typically, the assembly steps take place on a carousel having a plurality of stations, at which the various components are up- or downloaded.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

- Figure 1** shows a perspective view of a cannula safety assembly of the invention in a stowed configuration prior to use;
- Figure 2** shows a partly cross-sectional side view of the cannula safety assembly of Figure 1 just prior to use with the needle shield removed;
- Figure 3** shows a partly cutaway side view of the cannula safety assembly of Figure 2 in the retracted safe position;
- Figure 4** shows a detailed cross-sectional side view along the lines 4-4 of Figure 1;
- Figure 5** shows a detailed cross-sectional side view of part of the needle and viewing chamber assembly in the retracted position;
- Figure 5A** shows an end-on rear view of the viewing chamber of Figure 5;
- Figure 6** shows a perspective view of a retractor forming part of the cannula safety assembly of the invention;

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**Figures 7A to 7D** show partly schematic diagrams of various steps in the manufacturing process whereby a sealing plug is fitted to the needle;

**Figures 8A & 8B** show respective partly schematic top plan and rolled out side views of various steps in an automated assembly sequence adopted during the manufacturing process.

#### **DESCRIPTION OF EMBODIMENTS**

Referring first to Figures 1 to 3, a cannula safety assembly 82 includes a round cylindrical cannula safety shield 84 having a rear open end 85, an elongate retractor 86 which fits over the safety shield 84, and a needle assembly 88 which locates within the safety shield 84 when in the retracted Figure 3 position. A cannula or catheter tube 90 is formed with a rear hollow seat portion 92 which locates in a friction fit over a spigot 94 defined at the front end of the safety shield 84. A needle cover or shield 96 is in turn fitted over the front end of the safety shield, providing a protective cover for the needle assembly 88 and cannula 90 when in the extended position.

The retractor 86 is provided with a central shaft or plunger 98 which extends through the rear open end 85 of the safety shield and terminates in a balled end 100. A pair of caliper arms 102 extend in a direction parallel to the central shaft 98, and have opposed complementary concave arcuate faces 103 which allow them to fit snugly around the safety shield, as is clear from Figure 6.

Figures 4 and 5 show clearly how the various components described above fit together when assembled. The needle assembly 88 comprises a needle 106 fitted to a transparent needle seat 108, which also defines a viewing chamber 110. A filter disc 112 is mounted in a detent channel defined by first and

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second shoulders 114 and 138 respectively at a rear end of the viewing chamber, and is held firmly in position by the balled end 100 of the shaft, which in turn locates within a complementary socket-defining channel 116 located towards the rear of the needle assembly. A rubber sealing plug 118 is located snugly within the safety shield just rearwardly of the spigot 94. The sealing plug 118 is retained in position by means of a circumferential retaining rib 120 having a shallow sawtooth profile.

The needle and catheter shield 96 is dimensioned to slide snugly over the front end of the safety shield. A clip-receiving recess 122 is formed at the rearmost end of the needle shield 96, and is arranged to accommodate complementary clips 124 extending from the front end of the retractor calipers 86 when in the stowed position. The needle shield 96 and the retractor 86 thus mate with one another in a click fit to hold the entire assembly firmly together in the stowed needle-extended position.

In use, the cannula safety assembly 82 is operated as follows. Finger pressure is applied inwardly against the opposed flexible finger grips 126 at the ends of the caliper arms 102, and the needle shield is then pulled off as the clips 124 are released from the clip-receiving apertures 122. The cannula safety assembly is now in its Figure 2 condition, at which stage the practitioner continues to grip the cannula safety assembly around the finger grips 126 and introduces the sharp end 128 of the needle into the vein. The inner arcuate concave surfaces 103 of the calipers 86 deform inwardly when gripped so as to provide frictional resistance over a significant area of the outer arcuate, concave surfaces 84.1 of the safety shield. Forward pressure on the finger grips 128 is transmitted into forward pressure on the central shaft 98, which in combination with the frictional resistance between the calipers 86 and the safety shield 84 effectively overcomes any counter forces on the needle during the hypodermic insertion procedures. Once the cannula 90 is in place in the vein, which is indicated by the backflow of blood into the viewing chamber 110,

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the practitioner grips the front end 130 of the safety shield to prevent the cannula catheter from dislodging from the spigot 94, and simply withdraws the retractor 86 with the other hand with lightened pressure on the finger grips 126. The needle assembly 88 can thus be freely retracted to the Figure 3 position in which the aperture formed by the needle 106 through the rubber sealing plug 118 seals off, so as to prevent the continued backflow of blood into the safety shield.

It will be appreciated that, once disengaged from the needle shield, in the absence of any click- or rotary-type detent the retractor is able to travel freely in concert with the needle assembly from the extended administering position to the fully retracted position. The entire procedure involves a smooth axially reciprocating motion which is substantially jerk free and which does not deviate significantly from a conventional catheter insertion procedure.

A retaining rib 132 extending inwardly from the rear end of the shield serves to hold the needle assembly 88 captive within the chamber by abutting against a rearmost disc-shaped castellated flange 134 formed at the rearmost end of the needle assembly. The flange forms a sliding fit with the inner wall 136 of the safety shield, and is provided with six evenly spaced breather gaps 140 for ensuring that a vacuum is not formed in the space 141 between the needle assembly 88 and the shield 82. Further rearward force on the retractor causes the ball 100 to break away from the socket 116. During breakaway of the ball 100, additional outward pressure is exerted on the flange 134, thereby ensuring that the flange 134 is retained firmly in position behind the rib 132. The porous membrane 112, which was previously mechanically locked in position by the front face of the ball 100, is now retained by a rear shoulder 138 to prevent blood from escaping from the viewing chamber 110. The provision of both the sealing plug 118 and the filter disc 112 allow the practitioner to have sufficient time to arrange for a fluid line to be connected, without being concerned about the uncontrolled backflow of fluid through the

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catheter once the needle has been withdrawn through it. The combination of the air permeable filter disc 112 and breather gaps defined by flat faces 148 on either side of the ball 100 provide an air escape path as blood is introduced into the viewing chamber 110.

Referring now to Figures 7A to 7D, the various manufacturing steps involved in locating the disc-shaped sealing plug 118 concentrically over the needle 106 are shown. The needle assembly 88 stops at a sealing plug station 149, where a sheet of sealing plug rubber 150 is located between a die and punch assembly comprising an apertured die 152A, a stripper plate 152B and a circular punch 153. The needle is positioned in such a way that it is co-axial with the axis 154 defined by the die apertures. The needle is then clamped into position by means of a pair of clamps 156, after which the punch and die assembly is moved to the right, thereby causing the needle to pierce the strip of sealing plug material 150. The sealing plug material 150 is flexible, and re-aligns itself with the needle, whereafter the punch 153 moves to the right to cut the sealing plug 118, which is now concentrically located on the needle in the correct axial position along the needle. The punch then retracts, the needle moves on, and the strip of sealing plug material 150 indexes to the next position.

The various steps involved in the manufacture and insertion of the filter disc 112 are similar to those involved in manufacturing and placing the sealing plug, in that a die and punch assembly is used to punch filter discs from an indexed sheet of filter disc material, with the punch being arranged to locate the filter disc in the appropriate position within the viewing chamber.

Figures 8A and 8B illustrate the manner in which the cannula safety assembly is manufactured in a fully automated manufacturing procedure. The entire assembly procedure takes place on a carousel 160 which rotates relative to a barrel or safety shield loading station 162, a catheter loading station 164, a

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needle assembly loading station 166, a retractor loading station 168, a retractor inserting station 170 and a needle shield loading station 172. The completed assembly is rotated through one more step before being released for packaging at a packaging station 174. For ease of reference, the various stations have also been numbered from 1 to 8.

Referring now to Figure 8B, at the shield loading station 162, cannula safety shields 84 are drop loaded and then clamped in position. A string of catheters 90 is then provided in a drop tube or bandoleer, with each catheter then being individually uploaded from the drop tube or bandoleer via a reciprocating ram arrangement 176. At the needle loading station 166, a string of needle assemblies is then sequentially drop loaded into the rear open end of each needle shield 84. The needle assemblies are pre-fitted with the sealing plugs 118 and filter discs 112 in the manner described earlier on in the specification. At the retractor loading station 168, the central shafts or plungers 98 of a string of retractors 86 are drop loaded into the rear end of each needle shield 84. At the retractor inserting station 170, the retractor shaft 98 is inserted completely into the safety shield 84 by a plunger 178, thereby pushing the needle assembly through the safety shield to the Figure 2 extended position, with the ball 100 of the retractor holding the filter disc 112 in position.

At the needle shield loading station 172, the needle shields 96 are uploaded from a drop tube or bandoleer, with a ram 180 serving to urge the needle shield 96 into position in which it forms a click fit with the end of the retractor in a manner previously described. The complete cannula safety assembly 82 is then conveyed to the packaging station 174.

It is clear from the above that the cannula safety assembly of the invention lends itself readily to a high speed automated manufacturing and assembly process. This process is further speeded up by virtue of the fact that the entire assembly is mechanically fitted together, with no adhesives or bonding agents

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being required in the manufacturing process apart from the bonding of the needle to the needle seat.

It will also be apparent that because the rear of the needle assembly 88 in the safe position is substantially flush with the rear of the cannula safety shield 84, the overall length of the safety shield necessary to shroud the needle point 128 in the safe position approximates closely the overall length of the needle assembly.



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**CLAIMS**

1. A safety assembly for a hypodermic applicator set comprising a needle assembly including a needle seat from which a hollow needle extends, an elongate retractor which is mountable to the needle seat, a safety shield for housing the needle assembly slidably within a chamber defined therein and having a front end through which the needle is arranged to project and a rear open end through which the elongate retractor extends into mounting engagement with the needle seat, and at least one captivating formation carried on the shield, the needle assembly being slidably moveable in concert with the retractor from an extended administrable position in which the needle extends through the front end of the shield to a retracted position in which the needle is fully withdrawn into the chamber by the retractor to be held safely captive within the chamber by the captivating formation.
2. A safety assembly according to claim 1 in which the retractor is detachably mountable to a rear end of the needle seat and is separable from the needle seat when in the retracted position.
3. A safety assembly according to either one of claims 1 or 2 in which the retractor includes a pair of manually grippable outer caliper arms which are arranged to deform inwardly in response to finger pressure so as to frictionally engage an outer surface of the safety shield when the needle assembly is in the extended administrable position, and a central shaft or plunger which extends into the chamber and terminates in a needle seat engaging formation.
4. A safety assembly according to claim 3 in which the needle assembly and the refractor are in conjunction freely and axially slidable from the extended to the retracted positions, the caliper arms having an inner

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arcuate profile which corresponds to an outer arcuate profile of the safety shield.

5. A safety assembly according to either one of claims 3 or 4 in which a needle shield is fitted over the needle when in an extended position, the needle shield being mountable to a front end of the safety shield or retractor and including detent means for detaining the needle assembly in an extended stowed position prior to use.
6. A safety assembly according to claim 5 in which the needle shield and the retractor carry respective engaging and complementary engaging formations constituting the detent means for detachably engaging one another when the safety assembly is in the extended stowed position.
7. A safety assembly according to claim 6 in which the outer caliper arms terminate in the complementary engaging formations for engaging with engaging formations on the needle shield.
8. A safety assembly according to claim 7 in which the needle seat defines a viewing chamber for monitoring the ingress of fluid via the hollow needle, and fluid retaining filter insert means is mounted at a rear end of the viewing chamber, the filter insert means being held in position by the needle seat engaging formation at a front end of the plunger.
9. A safety assembly according to claim 8 in which the filter insert means comprises an air permeable filter disc which is mounted in a detent towards a rear end of the viewing chamber.
10. A safety assembly according to claim 9 in which the needle seat engaging formation comprises a balled end formation which is

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detachably engageable with a corresponding socket recess defined at a rear end of the viewing chamber, and at least one breather gap being defined between the ball end formation and the socket recess, with the combination of the air permeable filter disc and the breather gap providing an air escape path as fluid is introduced into the viewing chamber.

11. A safety assembly according to any one of the preceding claims in which the hypodermic applicator set is a hypodermic cannula set, the needle extends through a spigot defining a finger barrier at the front end of the safety shield, and a cannula or catheter tube is detachably mountable to the spigot.
12. A safety assembly according to claim 11 in which a sealing plug is located towards the front end of the chamber for preventing the leakage of fluid from the catheter tube into the chamber, the needle extending in use through the sealing plug in the extended position and being withdrawable back through the sealing plug to the retracted position in which the sharp end of the needle is seated rearwardly of the sealing plug, the sealing plug being arranged to reseal on withdrawal of the needle.
13. A safety assembly according to claim 12 in which the sealing plug serves as a front captivating formation for preventing the needle from escaping through the front end of the safety shield when in the retracted position.
14. A safety assembly according to any one of the preceding claims in which the captivating means comprises a retaining rib extending inwardly from a rear end of the shield, and a rearmost flange is formed at a rearmost end of the needle assembly, the flange forming a snug

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sliding fit with the inner wall surface of the safety shield and being provided with at least one breather gap for preventing the formation of a vacuum in that portion of the chamber between the needle assembly and the shield

15. A method of manufacturing a safety assembly for a hypodermic applicator set comprising the steps of providing a safety shield having a front spigot end and a rear open end, fitting a catheter tube to the front spigot end of the safety shield, loading a needle assembly, which includes a needle projecting from a needle seat, through the rear open end of the shield, and driving the needle assembly into an extended position in which the needle extends through the catheter tube using a retractor having a central plunger or shaft which detachably engages a complemental formation at a rear end of the needle seat.
16. A method according to claim 15 which includes the further steps of fitting a needle shield over the needle and catheter, with a rear end of the needle shield detachably engaging a front end of the retractor.
17. A method according to either one of claims 15 or 16 in which the method includes the further steps of fitting a sealing disc to the needle by piercing a sheet of disc-forming material with the needle, and using the needle as a centering axis for punching or cutting out the sealing disc.
18. A method according to claim 17 which includes the further step of locating the sealing disc towards the front end of a chamber defined within the safety shield for preventing the leakage of fluid from the catheter tube into the chamber once the needle is withdrawn into the retracted position.

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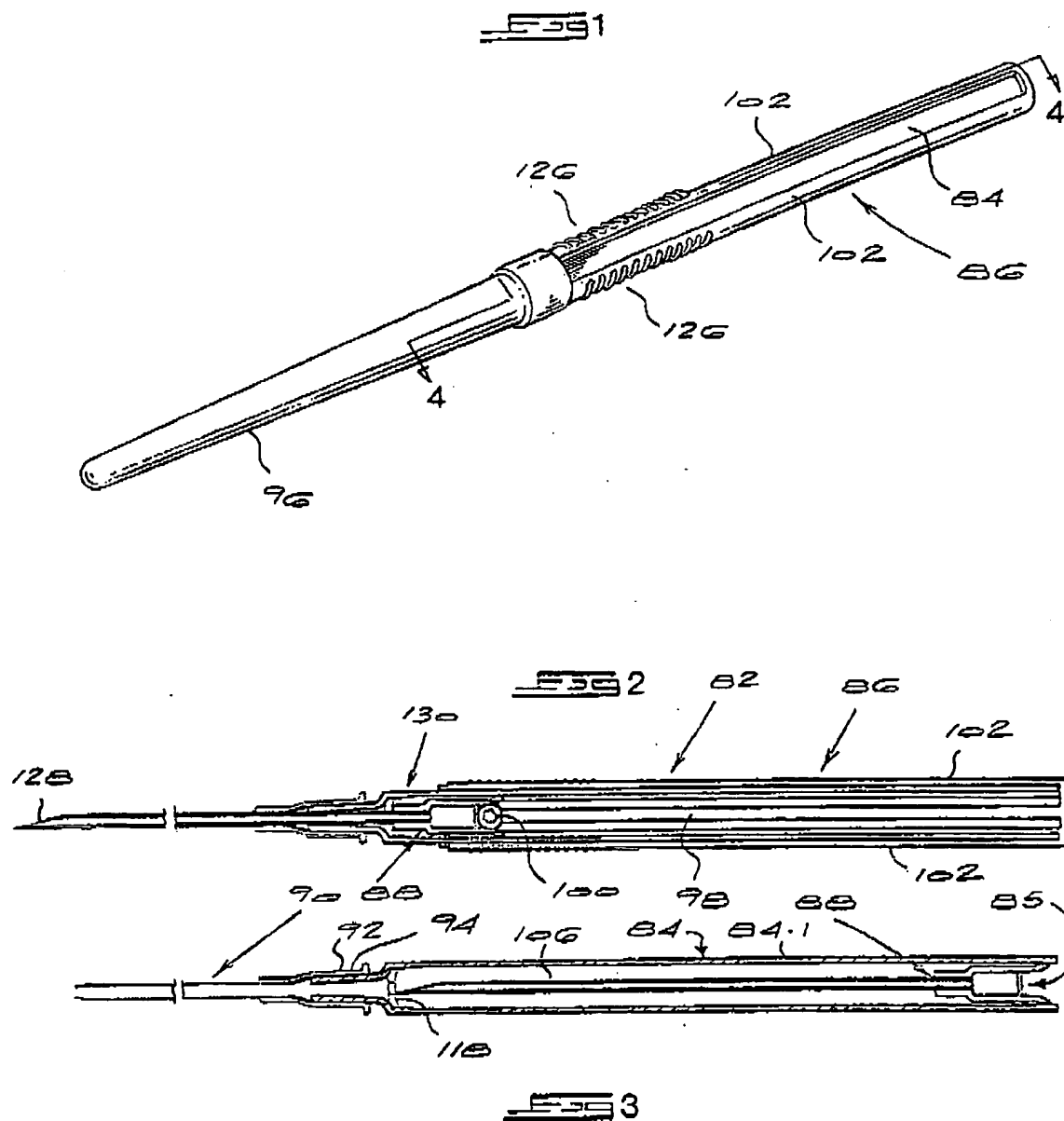
19. A method according to any one of the preceding claims 15 to 18 in which the method includes the further step of punching a filter disc from a sheet of disc material, locating the filter disc within the needle seat, and retaining the filter disc in position within the needle seat by virtue of the engagement between the central plunger or shaft and the complementary formation at the rear end of the needle seat.
20. A method according to any one of claims 15 to 19 in which the assembly steps take place on a carousel having a plurality of stations, at which the various components are up- or downloaded.

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FIG 4

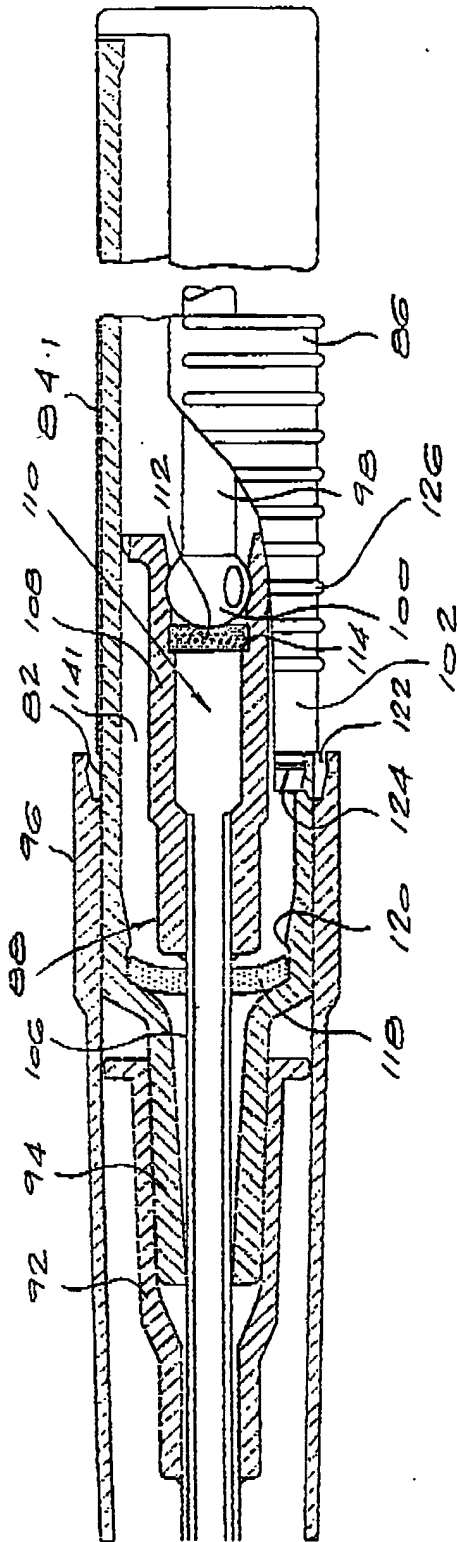
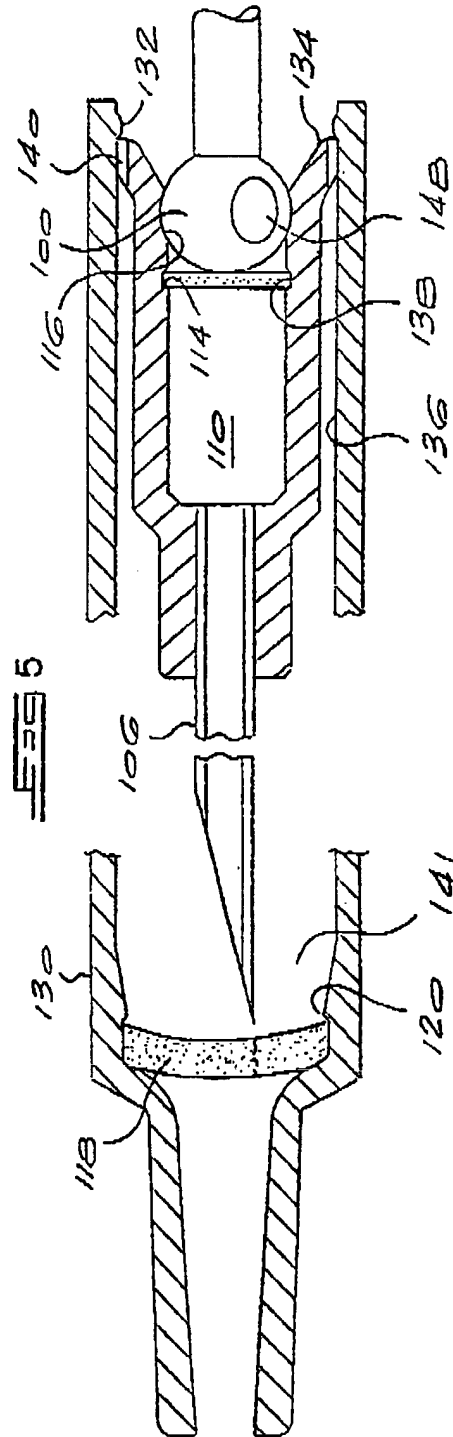


FIG 5



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FIG 5A

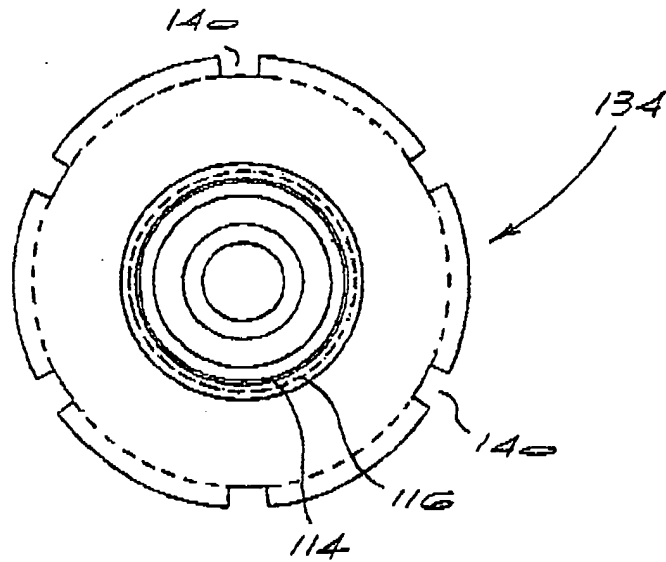
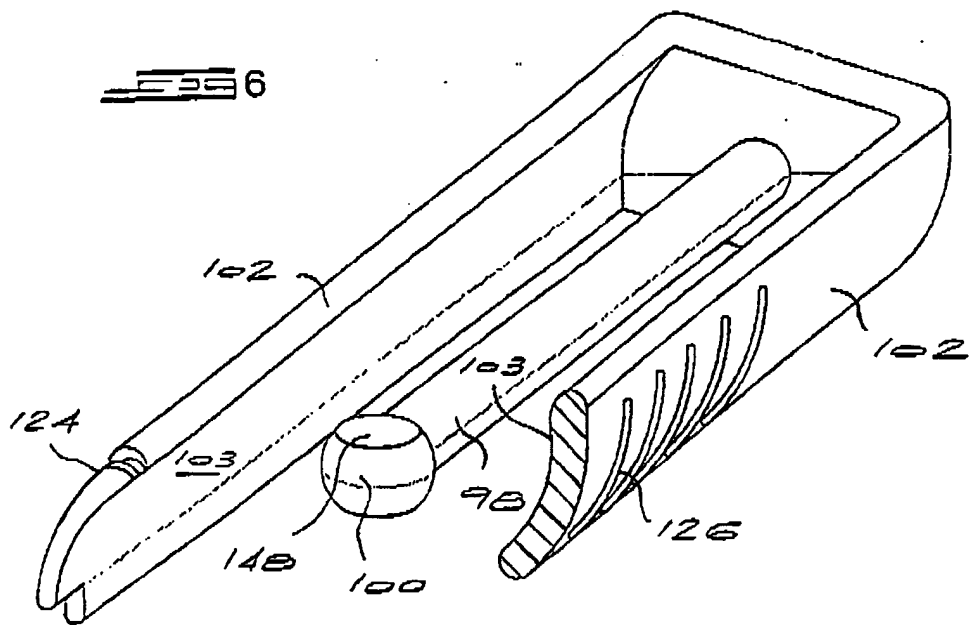


FIG 6



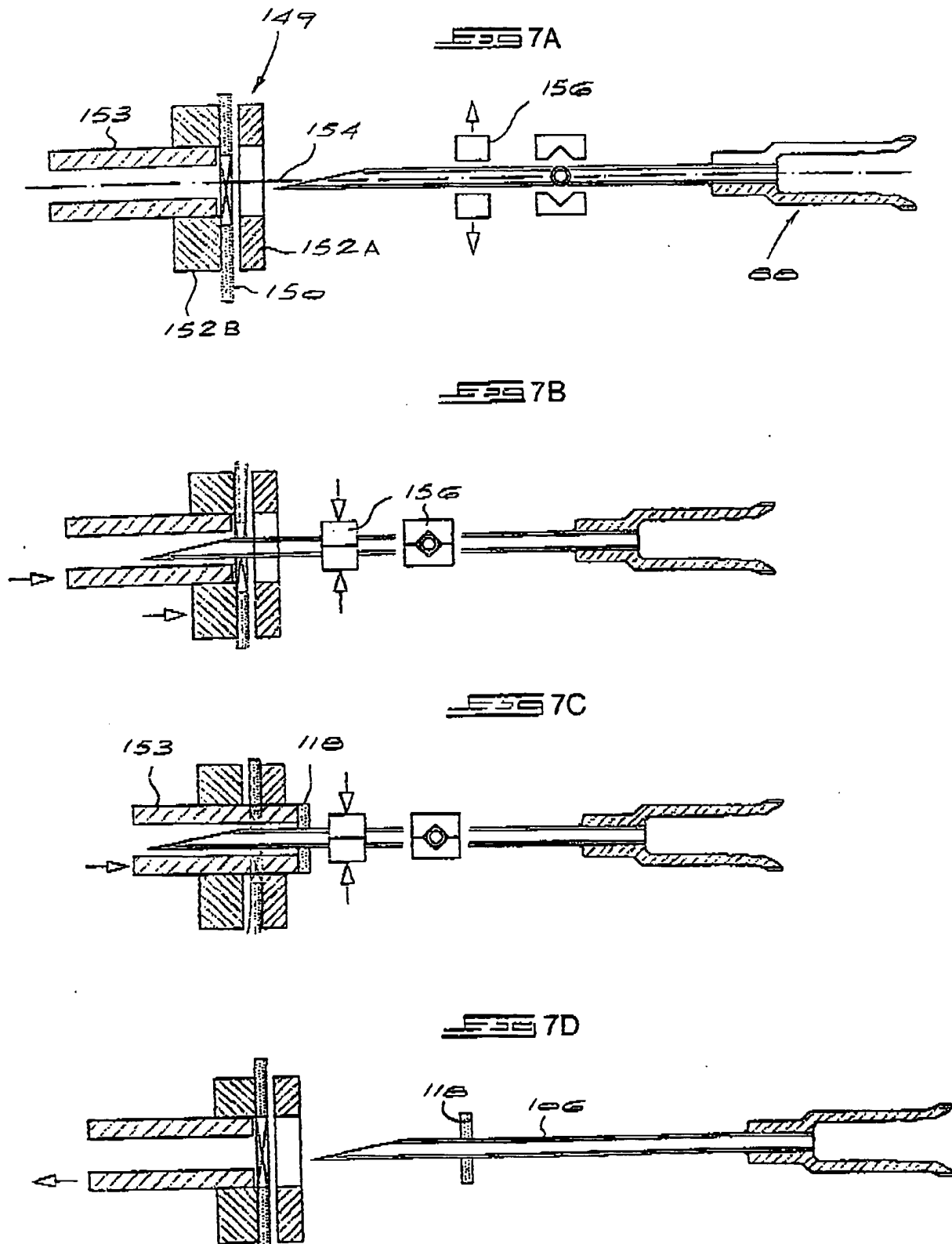


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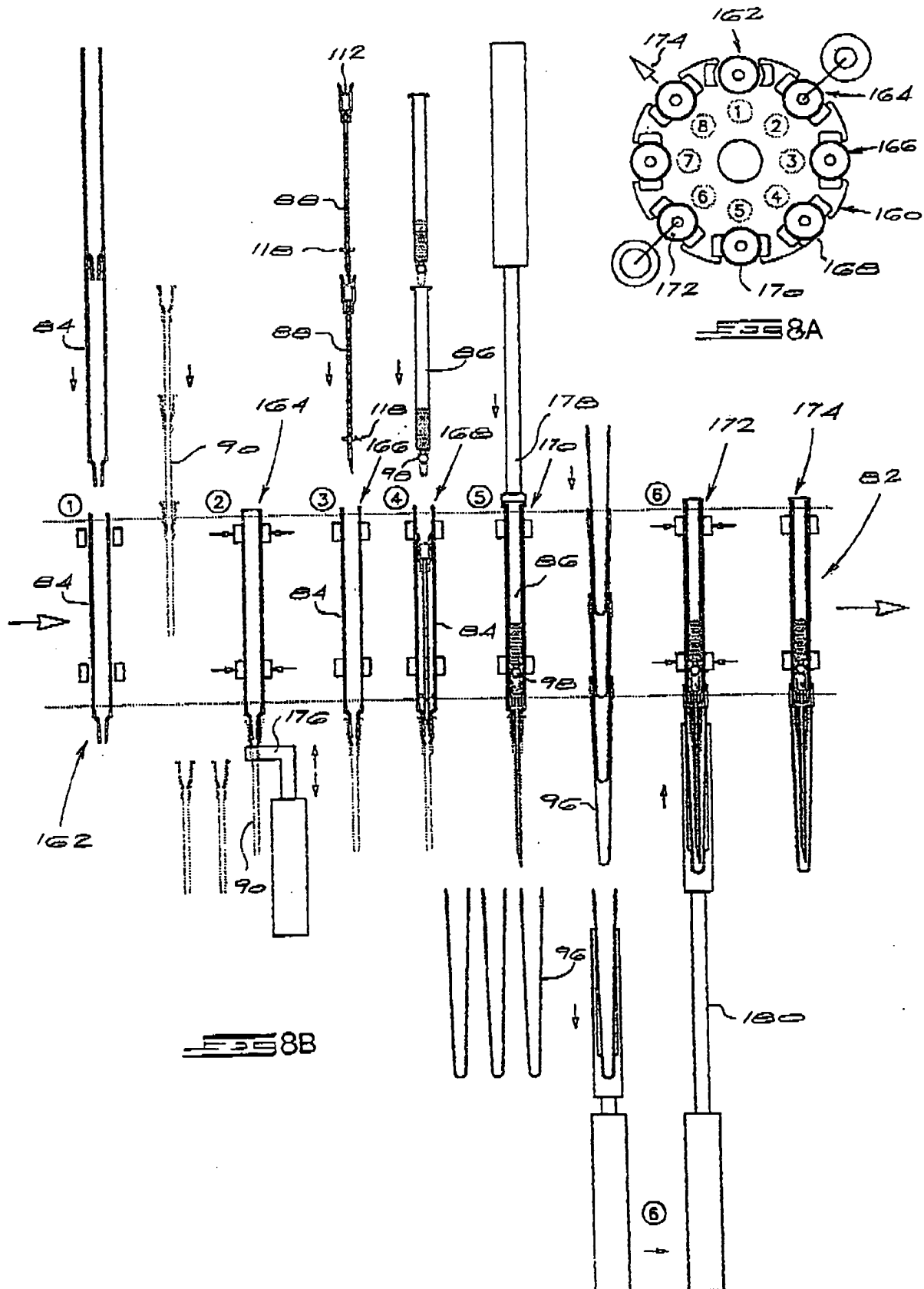


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## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/IB 00/00287

A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 7 A61M25/06 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 762 516 A (CHOKSI PRADIP V ET AL) 9 August 1988 (1988-08-09) column 2, line 9 - column 3, line 5; figures 1-4	1,2
X	US 5 769 827 A (DEMICHELE LOUIS R ET AL) 23 June 1998 (1998-06-23) abstract	1
Y	US 4 944 728 A (CARRELL MICHAEL W ET AL) 31 July 1990 (1990-07-31) abstract	1-14
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Further documents are listed in the continuation of box C.



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Date of the actual completion of the international search

20 June 2000

Date of mailing of the international search report

30/06/2000

Name and mailing address of the ISA

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 Fax: (+31-70) 340-3016

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Ehram, F

## INTERNATIONAL SEARCH REPORT

Inter Application No

PCT/IB 00/00287

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 382 190 A (SAFETYJECT) 16 August 1990 (1990-08-16) abstract	1
A	US 4 944 725 A (MCDONALD MICHAEL) 31 July 1990 (1990-07-31) the whole document	1-14
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A	WO 92 09320 A (NUJENKO PTY LTD) 11 June 1992 (1992-06-11) figures 14-16	10
A	US 5 403 283 A (LUTHER RONALD B) 4 April 1995 (1995-04-04) figures 5-10	1
A	DE 44 34 569 A (BECTON DICKINSON CO) 30 March 1995 (1995-03-30) figures 8-10	12

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International Application No

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			JP 7163665 A	27-06-1995

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>W/D/127</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/IB 00/ 00287</b>	International filing date (day/month/year) <b>17/03/2000</b>	(Earliest) Priority Date (day/month/year) <b>17/03/1999</b>
Applicant  <b>DUGMORE, Peter, Balfour et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

4

☐ None of the figures.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 00/00287

A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 7 A61M25/06 A61M5/32

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IPC 7 A61M

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Y	GB 2 202 747 A (DUCAT DR WILLIAM) 5 October 1988 (1988-10-05) page 5, line 16 - line 20; figure 4 --- -/--	1-14

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Name and mailing address of the ISA

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## INTERNATIONAL SEARCH REPORT

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A	DE 44 34 569 A (BECTON DICKINSON CO) 30 March 1995 (1995-03-30) figures 8-10 -----	12

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Information on patent family members

International Application No

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